

REMARKS

Claims 9-13 are pending in this application. Claims 1-3, 5-7 and 14 have been canceled. Claim 9 has been amended. No new matter has been introduced.

Claims 9-13 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Fucci et al. (U.S. Patent No. 5,697,950) ("Fucci") in view of Chan (U.S. Patent No. 6,629,984) ("Chan"). This rejection is respectfully traversed.

The claimed invention relates to a method of securing tissue to bone by using suture. Amended independent claim 9 recites a "method of securing tissue to bone using a length of suture" by *inter alia* "installing a suture anchor with an attached suture strand in a portion of bone adjacent a section of tissue to be secured," "piercing said tissue with a sharp distal end of a cannulated suture passing instrument" and "passing a strand of flexible metallic material, formed into an elongated loop having a crimped end with an acute bend, through the cannulated suture passing instrument." Amended independent claim 9 also recites "deploying said loop . . . from the sharp distal end of said cannulated suture passing instrument," "capturing said suture strand with said loop" and "passing said captured suture strand through said tissue by retracting the loop through the tissue."

Fucci relates to a device that "enables a suture anchor to be preassembled with a suture so that a user need not assemble a suture anchor with suture immediately prior to use." (Abstract). Fucci teaches that "[t]he preassembled anchor/suture is provided with a suture stiffening or support member by which the free ends of the suture may be easily threaded into the axial bore of a cannulated driver." (Abstract). According to Fucci, "[t]he support member may comprise a length of shrinkable tubing

frictionally engaging at least a portion of the free ends of the suture extending from the anchor.” (Abstract).

Chan relates to a “suture passer including a longitudinally-extending hollow cannula having a central passage slidably receivable of a surgical suture; a manually graspable handle connected to the hollow cannula for manipulation thereof, the handle having an upper surface; a first guide, connected to the upper surface of the handle, proximate a distal end of the handle, for releasably, guidingly holding the surgical suture; and a second guide, connected to the upper surface of the handle, proximate to the first guide, for releasably, guidingly holding the surgical suture.” (Abstract). Chan teaches that “[t]he suture passer can be provided in a kit, for use in the suturing of internal tissue, along with a cannula bender, various hollow surgical needles and surgical suture material.” (Abstract).

The subject matter of claims 9-13 would not have been obvious over Fucci in view of Chan. Specifically, the Office Action fails to establish a *prima facie* case of obviousness. Courts have generally recognized that a showing of a *prima facie* case of obviousness necessitates three requirements: (i) some suggestion or motivation, either in the references themselves or in the knowledge of a person of ordinary skill in the art, to modify the reference or combine the reference teachings; (ii) a reasonable expectation of success; and (iii) the prior art references must teach or suggest all claim limitations. See e.g., In re Dembiczak, 175 F.3d 994 (Fed. Cir. 1999); In re Rouffet, 149 F.3d 1350, 1355 (Fed. Cir. 1998); Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc., 75 F.3d 1568, 1573 (Fed. Cir. 1996).

First, not all limitations of amended independent claim 9 are disclosed, taught or suggested by the prior art references, whether considered alone or in combination. Fucci does not disclose, teach or suggest “piercing said tissue with a

sharp distal end of a cannulated suture passing instrument," much less "piercing said tissue with a sharp distal end of a cannulated suture passing instrument," "passing a strand of flexible metallic material, formed into an elongated loop having a crimped end with an acute bend, through the cannulated suture passing instrument," "deploying said loop . . . from the distal end of said suture passing instrument," "capturing said suture strand with said loop" and "passing said captured suture strand through said tissue by retracting the loop through the tissue," as in the claimed invention. Fucci relates to a method of providing a pre-loaded suture anchor assembly for attachment to a suture anchor driver, and not to a method of securing tissue to bone, much less to a method of securing tissue to bone by the specific steps of the claimed invention.

Similarly, Chan fails to disclose, teach or suggest all limitations of amended independent claim 9. Chan teaches that "[b]y careful manipulation, a suture 43 is fed through the needle and into the cannula" so that "[w]ith the tip of the cannula and the needle securely engaged, the suture is fed (FIG. 18) into the hub of the needle until it exits the proximal end of the cannula at the handle of the suture passer." (Col. 16, lines 16-20). In this manner, "[t]he suture is then looped onto the distal guide and is threaded back into the cannula" and "[t]he suture is then engaged onto the proximal guide (FIG. 19)." (Col. 16, lines 21-24). Thus, Chan does not disclose, teach or suggest "passing a strand of flexible metallic material, formed into an elongated loop having a crimped end with an acute bend, through the cannulated suture passing instrument," "deploying said loop . . . from the distal end of said suture passing instrument," "capturing said suture strand with said loop" and "passing said captured suture strand through said tissue by retracting the loop through the tissue," as recited in claim 9.

Second, Applicant notes that a person of ordinary skill in the art would not have been motivated to combine Fucci with Chan to arrive at the claimed invention. Fucci relates to a "pre-loaded suture anchor assembly for attachment to a suture anchor driver." (Col. 3, lines 19-21). For this, Fucci teaches an "anchor/suture assembly" which may be employed with a rod that can be "threaded into a cannulated driver simply by the force of gravity acting upon the rod." (Abstract). On the other hand, Chan relates to a surgical repair kit for passing a length of suture through a needle and into a cannula and then into the tissue. Chan teaches an instrument having "a handle and various interchangeable cannulas, with each cannula being adapted to be releasably and lockingly held by the handle during a surgical procedure." (Col. 3, 42-54). Accordingly, a person of ordinary skill in the art would not have been motivated to combine the pre-loaded suture anchor assembly of Fucci with the suturing kit of Chan having suture threaded through a needle and into a cannula with first and second guides.

Applicant also notes that courts have held that "[i]f the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious." M.P.E.P. § 2143.01 (citing In re Ratti, 270 F.2d 810 (CCPA 1959). This is because the "suggested combination of references would require a substantial reconstruction and redesign of the elements shown in [the primary reference] as well as a change in the basic principle under which [the primary reference] construction was designed to operate." In re Ratti, 270 F.2d at 813.

In the present case, employing the suturing kit of Chan having suture threaded through a needle and into a cannula with the pre-loaded suture anchor assembly of Fucci, as the Office Action suggests, "would require a substantial

reconstruction and *redesign* of the elements shown in [Fucci] (emphasis added)." Thus, the suggested combination of Fucci and Chan would have to eliminate the pre-loaded suture anchor assembly of Fucci to allow the cannulas of Chan having various configurations (which are used for a simple suture passing through a needle) to be employed *in lieu* of the suture/anchor driver of Fucci and, thus, redesign and reconstruct the elements of Fucci. For at least these reasons, the Office Action fails to establish a *prima facie* case of obviousness and withdrawal of the rejection of claims 9-13 is respectfully requested.

Allowance of all pending claims is respectfully solicited.

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